2012 Bone and Muscle Risk Standing Review Panel

Research Plan Review for:

The Risk of Bone Fracture
The Risk of Early Onset Osteoporosis Due To Spaceflight

Final Report

I. Executive Summary and Overall Evaluation

The 2012 Bone and Muscle Risk Standing Review Panel (from here on referred to as the SRP) met for a site visit in Houston, TX on October 24 - 25, 2012 to review the Research Plan for the two bone risks (Risk of Bone Fracture and the Risk of Early Onset Osteoporosis Due to Spaceflight) in the Human Research Program's (HRP) Integrated Research Plan (IRP Rev. D).

The SRP commends and was very pleased with the increased interactions of the bone discipline with others in the musculoskeletal research community, such as the invited participants at the Bone Summit (June 2010) and the formal activities with the musculoskeletal scientists currently funded through the National Space Biomedical Research Institute (NSBRI).

The SRP still strongly urges increased research use of the astronaut databases (Lifetime Surveillance of Astronaut Health and Life Sciences Data Archive). The SRP thinks that this may require finding resources and means for complex bioinformatics to examine potential predictors of bone loss (e.g., nutrition, endocrine, immune, radiation). Advanced methods may be required to account for missing data, repeated measures, changes in assays, consistency in nomenclature, etc. Along these lines, the SRP strongly recommends for ISS data utilization. The new international co-operations raise opportunities to leverage data for larger numbers of subjects. To do so, there is the need to establish standards for data entry (e.g., dates and times), defined standards of measurements, and data sharing plans.

Some concern was raised by the SRP for the quantitative computed tomography based finite element method (QCT FEM) regarding the risk to benefit ratio, given the concern of increased radiation exposure to determine whether a surrogate for bone strength is "improved" relative to another. There was also some concern that the observed low fracture incidence in a comparable age group makes difficult the goals to define long-term fracture risk due to spaceflight missions and to determine the utility of surrogate measurements.

The SRP is enthusiastic about ongoing efforts to assess the suitability of ultrasound to monitor rates of bone changes, fracture detection, and fracture healing during spaceflight.

The SRP recommends that factors other than microgravity that are encountered in the spaceflight environment be assessed for their contribution to bone and muscle loss.

II. Critique of Gaps and Tasks for the Risk of Bone Fracture

- The SRP thinks that all three of the Gaps under the Risk of Bone Fracture are clear, well worded, and pertinent.
- The SRP recommended that prioritization of the tasks may be helpful to develop metrics

for gap closure decisions.

Gaps and Tasks:

Fracture 1 (B31): We don't understand how the spaceflight environment affects bone fracture healing in-flight.

Task:

- Fracture Healing in Haversian Bone under Conditions of Simulated Microgravity PI: Christian Puttlitz, Ph.D., Colorado State University
 - o The SRP thinks this task is appropriate for this particular Gap.
- Extent, Causes, and Countermeasures of Impaired Fracture Healing in Hypogravity PI: Ronald Midura, Ph.D., Cleveland Clinic Lerner Research Institute
 - The SRP thinks this task is appropriate for this particular Gap.
- Combined Scanning Confocal Ultrasound Diagnostic and Treatment System for Bone Quality Assessment and Fracture Healing – PI: Yi-Xian Qin, Ph.D., SUNY- The State University of New York
 - o The SRP thinks this task is appropriate for this particular Gap.
- Astronaut Bone Medical Standards Derived from Finite Element [FE] Modeling of QCT Scans from Populations Studies PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
 - o The SRP does not think this task is applicable to this particular Gap.
- A Scanning Confocal Acoustic Diagnostic System for Non-Invasively Assessing Bone Quality PI: Yi-Xian Qin, Ph.D., SUNY- The State University of New York
 - o The SRP does not think this task is applicable to this particular Gap.
- Ultrasound Add-On to Puttlitz Planned task
 - The SRP thinks this task is appropriate for this particular Gap.

Fracture 2 (B30): We need to characterize the loads applied to bone for standard inmission activities.

Tasks:

- Ultrasound Add-On to Puttlitz Planned task
 - The SRP does not think that this task is clearly applicable for this particular Gap.
- Digital Astronaut: Bone Physiology Model Planned task
 - The SRP thinks that this task is appropriate, but the SRP does not have sufficient information about the "Digital Astronaut: Bone Physiology Model" to determine its contribution to closing this Gap

Fracture 3 (B30): We need a validated method to estimate the risk of fracture by evaluating the ratio of applied loads to bone fracture loads for expected mechanically-loaded activities during a mission.

• It is not clear to the SRP as to whether any of the listed tasks listed below really address the real issues raised by this Gap.

- Feasibility Study: QCT Modality for Risk Surveillance of Bone Effects of In-flight Countermeasures on Sub-regions of the Hip Bone PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Assess Vertebral Compression Fractures (MRID) Planned task
- SPRINT Optimization Studies Planned task
- Digital Astronaut: Bone Physiology Model Planned task

Proposed New Tasks:

- The SRP suggests that a task be added that includes an analysis of current astronauts' post-flight hip QCT with FE modeling of bone strength. This may supply the "denominator" for the desired ratio in the Gap Fracture 3 and the answer to Gap Fracture 2 should supply the "numerator" for the desired ratio.
- The SRP recommends that factors other than microgravity that are encountered in the spaceflight environment be assessed for their effects on fracture healing in order to develop new tasks that are comprehensive relative to the Gap.

III. Critique of Gaps and Tasks for the Risk of Early Onset Osteoporosis Due To Spaceflight

- The SRP suggests changing the Risk title to: "Early Onset Osteoporosis /Abnormal Premature Bone Loss from Long Duration Spaceflight".
- Overall, the SRP believes that all seven of the Osteo Gaps (listed below) can be written in a better way that clarifies the goals of the tasks, and hence, the deliverables. For example, Osteo 1 needs to include 1) predictive fracture risk capabilities of a proposed surrogate for bone strength and 2) comparison with state of art bone mineral density (BMD) and advanced BMD-based structural analyses. There is concern that superiority of one approach over another cannot be determined with the Gaps as presented. It is not clear how criteria for a "non-permissible outcome" would be produced without this link to fracture data. It is not clear what the basis for standard would be without knowing the correlation with fracture risk.
- The SRP was concerned that the risk-to-benefit ratio for QCT was not addressed by the tasks, given the concern of increased radiation exposure if the goal is to determine whether a surrogate for bone strength is "improved" relative to another.
- The SRP had concern about the rationale to apply population data for QCT-FEM structural analysis for individual evaluations of an astronaut's fracture risk. A more developed rationale is needed to support this direction.

Gaps and Tasks:

Osteo 1: A new acceptable bone health standard using an improved surrogate for bone strength needs to be defined for the flight environment.

- Developing a new bone medical standard for long-duration astronauts based on bone strength estimated by Finite Element [FE] Modeling Task completed
 - o The SRP thinks this task is appropriate for this particular Gap.

- Astronaut Bone Medical Standards Derived from Finite Element [FE] Modeling of QCT Scans from Populations Studies – PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
 - The SRP thinks this task is appropriate for this particular Gap.
- Feasibility Study: QCT Modality for Risk Surveillance of Bone Effects of In-flight Countermeasures on Sub-regions of the Hip Bone PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
 - o The SRP thinks this task is appropriate for this particular Gap.

Osteo 2 (B1a & B29): What is the incidence & prevalence of early onset osteoporosis or fragility fractures due to exposure to spaceflight.

Tasks:

- Epidemiologic Analyses of Risk Factors for Bone Loss and Recovery Related to Long Duration SpaceFlight PI: Shreyasee Amin, M.D., Mayo Clinic College of Medicine
- Bone Epidemiologic Analysis II Planned task
- Feasibility Study: QCT Modality for Risk Surveillance of Bone Effects of In-flight Countermeasures on Sub-regions of the Hip Bone – PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Assess Vertebral Compression Fractures (MRID) Planned task

Osteo 3 (B1b & B29): We need a validated clinically relevant method for assessing the effect of spaceflight on osteoporosis or fracture risk in long-duration astronauts.

Tasks:

- Feasibility Study: QCT Modality for Risk Surveillance of Bone Effects of In-flight Countermeasures on Sub-regions of the Hip Bone - PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Assess Vertebral Compression Fractures (MRID) Planned task
- Bone Measures Add-On to OP Summit Follow-On Study Planned task

Osteo 4 (B1c, B11, N7): We don't know the contribution of each risk factor on bone loss and recovery of bone strength, and which factors are the best targets for countermeasure application.

- Epidemiologic Analyses of Risk Factors for Bone Loss and Recovery Related to Long Duration SpaceFlight – PI: Shreyasee Amin, M.D., Mayo Clinic College of Medicine
- Bone Epidemiologic Analysis II Planned task
- Feasibility Study: QCT Modality for Risk Surveillance of Bone Effects of In-flight Countermeasures on Sub-regions of the Hip Bone – PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Astronaut Bone Medical Standards Derived from Finite Element [FE] Modeling of QCT Scans from Populations Studies PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Nutritional Status Assessment: SMO-016E PI: Scott Smith, Ph.D., NASA Johnson Space Center

- SPRINT Optimization Studies Planned task
- An Integrated Musculoskeletal Countermeasure Battery for Long-Duration Lunar Missions PI: Thomas Lang, Ph.D., University of California, San Francisco
- Dietary Intake Can Predict and Protect Against Changes in Bone Metabolism During Spaceflight and Recovery (Pro-K) PI: Scott Smith, Ph.D., NASA Johnson Space Center
- Evaluate n-3 Fatty Acids as a Countermeasure for Bone Loss Planned task
- Bisphosphonates as a Countermeasure to Spaceflight Induced Bone Loss: SMO-021 PI: Adrian LeBlanc, Ph.D., USRA
- Bone Turnover Model: Initial Implementation PI: J.A. Pennline, Ph.D., NASA Glenn Research Center
- Contribution of the Vestibular and Sympathetic Nervous Systems to Space-Induced Bone Loss (NSBRI Postdoctoral Fellowship) – PI: Guillaume Vignaux, Ph.D., Vanderbilt University
- Contributors to Long-Term Recovery of Bone Strength following Exposure to Microgravity PI: Harry Hogan, Ph.D., Texas A&M University
- Evaluation of a Sclerostin Antibody in Mice as a Novel Promoter of Bone Formation During Spaceflight PI: Virginia Ferguson, Ph.D., University of Colorado at Boulder
- Ground-based Biomechanical Analyses of Resistance Exercise Using the Advanced Resistive Exercise Device – PI: John DeWitt, Ph.D., NASA Johnson Space Center
- Induction of Early Stages of Osteoarthritis After Exposure to Microgravity (NSBRI Postdoctoral Fellowship) PI: Liliana Mellor, Ph.D., Boise State University
- Integrated Resistance and Aerobic Training Study PI: Lori Ploutz-Snyder, Ph.D., NASA Johnson Space Center
- Maintaining Musculoskeletal Health in the Lunar Environment PI: Susan Bloomfield, Ph.D., Texas A&M University
- Pilot Studies of Radiation Damage in Organ Tissues of Mice PI: Jean Sibonga, Ph.D. NASA Johnson Space Center
- Recovery of Musculoskeletal Quantity and Quality upon Multiple Microgravity Exposure PI: Stefan Judex, Ph.D., SUNY- The State University of New York
- Simulated Microgravity and Radiation-Induced Bone Degeneration: Oxidative Stressand p53-Dependent Mechanisms – PI: Ruth Globus, Ph.D., NASA Ames Research Center
- Space Radiation and Bone Loss: Lunar Outpost Mission Critical Scenarios and Countermeasures PI: Ted Bateman, Ph.D., University of North Carolina at Chapel Hill
- Testosterone Supplementation as a Countermeasure against Musculoskeletal Losses during Space Exploration – PI: Randall Urban, Ph.D., University of Texas Medical Branch at Galveston
- Issues Related to Systemic Inflammatory Response Planned task
- Flywheel Prescription Optimization Planned task
- Development of New Exercise Hardware for Exploration Missions Planned task
- Biochemistry Profile Surveillance Planned task
- Integrated Regulation of Bone and Muscle Metabolism by Simulated Microgravity PI: Henry Donahue, Ph.D., Penn State College of Medicine
- Simulated Space Radiation and Weightlessness: Vascular Bone Coupling Mechanisms to Preserve Skeletal Health PI: Ruth Globus, Ph.D., NASA Ames Research Center

Osteo 5 (B10): We need an inflight capability to monitor bone turnover and bone mass changes during spaceflight.

Tasks:

- Nutritional Status Assessment: SMO 016E PI: Scott Smith, Ph.D., NASA Johnson Space Center
- Flexible Ultrasound Correlation to Bone Measures Planned task
- Validation of Bone Microarchitecture Technology Animal Study Planned task
- Validation of Bone Microarchitecture Technology Ground Study Planned task
- Validation of Bone Microarchitecture Technology Flight Study Planned task
- Feasibility Study: QCT Modality for Risk Surveillance of Bone Effects of In-flight Countermeasures on Sub-regions of the Hip Bone - PI: Jean Sibonga, Ph.D. - NASA Johnson Space Center
- Monitoring of Bone Loss Biomarkers in Human Sweat: A Non-Invasive, Time Efficient Means of Monitoring Bone Resorption Markers under Micro and Partial Gravity Loading Conditions – PI: Mark Clarke, Ph.D., University of Houston
- Rapid Measurements of Bone Loss Using Tracer-less Calcium Isotope Analysis of Blood and Urine PI: Ariel Anbar, Ph.D., Arizona State University
- Reusable Handheld Electrolytes and Lab Technology for Humans Task completed
- A Scanning Confocal Acoustic Diagnostic System for Non-Invasively Assessing Bone Quality PI: Yi-Xian Qin, Ph.D., SUNY The State University of New York
- Combined Scanning Confocal Ultrasound Diagnostic and Treatment System for Bone Quality Assessment and Fracture Healing – PI: Yi-Xian Qin, Ph.D., SUNY- The State University of New York
- Wideband Single Crystal Transducer for Bone Characterization PI: Kevin Snook, Ph.D., TRS Ceramics, Inc.
- Biochemistry Profile Surveillance Planned task

Osteo 6: How do skeletal changes due to spaceflight modify the terrestrial risk of osteoporotic fractures?

- Feasibility Study: QCT Modality for Risk Surveillance of Bone Effects of In-flight Countermeasures on Sub-regions of the Hip Bone - PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Epidemiologic Analyses of Risk Factors for Bone Loss and Recovery Related to Long Duration Spaceflight PI: Shreyasee Amin, M.D., Mayo Clinic College of Medicine
- Bone Epidemiologic Analysis II Planned task
- Astronaut Bone Medical Standards Derived from Finite Element [FE] Modeling of QCT Scans from Populations Studies PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Assess Vertebral Compression Fractures (MRID) PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Bisphosphonates as a Countermeasure to Spaceflight Induced Bone Loss: SMO-021 PI: Adrian LeBlanc, Ph.D., USRA
- Combined Scanning Confocal Ultrasound Diagnostic and Treatment System for Bone

Quality Assessment and Fracture Healing – PI: Yi-Xian Qin, Ph.D., SUNY- The State University of New York

Osteo 7 (B3, MO5, B15): We need to identify options for mitigating early onset osteoporosis before, during and after spaceflight.

• The SRP is enthusiastic for the plan to monitor advances in drugs for osteoporosis prevention for potential use as in-flight countermeasures.

Tasks:

- Feasibility Study: QCT Modality for Risk Surveillance of Bone Effects of In-flight Countermeasures on Sub-regions of the Hip Bone - PI: Jean Sibonga, Ph.D., NASA Johnson Space Center
- Bisphosphonates as a Countermeasure to Spaceflight Induced Bone Loss: SMO-021 PI: Adrian LeBlanc, Ph.D., USRA
- Emerging Drug (DMab) Analogue Validation Planned task
- Emerging Drug (DMab) Flight Validation Planned task
- Emerging Drug (TBD) Analogue Validation Planned task
- Emerging Drug (TBD) Flight Validation Planned task
- Nutritional Status Assessment: SMO-016E PI: Scott Smith, Ph.D., NASA Johnson Space Center
- Integrated Resistance and Aerobic Training Study (SPRINT) PI: Lori Ploutz-Snyder, Ph.D., NASA Johnson Space Center
- Integrated Resistance and Aerobic Exercise Training with Small Compact Exercise Equipment – Planned task
- Epidemiologic Analyses of Risk Factors for Bone Loss and Recovery Related to Long Duration SpaceFlight PI: Shreyasee Amin, M.D., Mayo Clinic College of Medicine
- Bone Epidemiologic Analysis II Planned task
- Evaluate n-3 Fatty Acids as a Countermeasure for Bone Loss Planned task
- Flight Validation of an Integrated Nutritional, Pharmaceutical and Exercise CM Planned task
- Pharmaceutical Countermeasure Effects on Tissue-level Quality of Immobilized Bone –
 PI: Devendra Bajaj, Ph.D., University of Medicine and Dentistry of New Jersey

IV. Discussion on the strengths and weaknesses of the IRP and identify remedies for the weaknesses, including answering these questions:

Is the Risk addressed in a comprehensive manner?

• The SRP thinks that both the Risk of Bone Fracture and the Risk of Early Onset Osteoporosis Due to Spaceflight are addressed in a comprehensive manner.

Are there obvious areas of potential integration across disciplines that are not addressed?

- The SRP thinks that most areas of integration have been addressed, but would like to reemphasize that the bone discipline group continue their integration and development of other Elements or disciplines that have great impact on musculoskeletal health, such as nutrition, radiation, immunity.
- The SRP also recommends that factors other than microgravity be assessed for

contributions to bone loss, (e.g., endocrine derangements, anti-oxidant reserves, sleep deprivation, radiation, etc.). This may lead to additional integration with other disciplines.

V. Evaluation of the progress in the IRP Rev. D since the 2011 SRP meeting.

The SRP found it a strength to clarify the Gaps by organizing the former Bone Risks into the topics of in-flight fracture risk and healing, on the one hand, and post-flight early onset osteoporosis and fracture risk, on the other.

The SRP appreciates that the overhaul of the Gaps was mandated to allow for a framework for metrics and closure decisions. The new Gaps were influenced by information that resulted from the 2010 Bone Summit. Because the history of the Gaps and tasks need to be traceable, it is important that there be a complete update of the Evidence Report that justifies the Gaps, as revised. It is commendable that there is a review article about this, but it should have been shared with the SRP. It is likely that more information is available for a detailed update of the Evidence Report to support the new Gaps.

The SRP found the IRP, Rev. D to be incomplete and missing information, specifically related to the tasks (Aims, Milestones, etc.). This made it difficult to assess whether the tasks were relevant and whether they would help close the Gap. The SRP requested a summary report of ongoing and planned tasks, not only by study titles, but by aims as they relate to addressing each Gap. The SRP had the impression that some of the listed tasks may not directly relate to the Gap. Having such a summary of achieved results and how they help towards closure of the Gap and expected outcomes of ongoing or planned tasks would have allowed the SRP to better evaluate whether the Risks are addressed in a comprehensive manner. On November 12, 2012, Jean Sibonga, Ph.D., the Bone Portfolio Lead Scientist, provided the SRP with a Word document which included the proposal title, the status of the task (active, completed, terminated, unfunded, or planned), description (specific aims/conclusions) of the task, and a general statement of how the task will contribute to the closure of the gap for both the Risk of Bone Fracture and the Risk of Early Onset Osteoporosis Due to Spaceflight. However, upon review of the information provided in this document, the SRP concludes that it is currently impossible to assess whether all the tasks are relevant and whether they help close the Gap.

The SRP recommends that the tasks be prioritized in relation to how their aims address each Gap.

VI. Additional Comments

The SRP thought that their charge was to provide input on the refined gaps for the Risk of Bone Fracture and the Risk of Early Onset Osteoporosis Due to Spaceflight so that closure could be defined and summarized so far on the tasks. The SRP could not assess this from the original review materials, from the oral/slide/discussion presentation, nor from the additional documentation that the SRP received after the October 24 – 25, 2012 meeting. The SRP would have liked to have seen a short table of the tasks for the Risk of Bone Fracture and the Risk of

Early Onset Osteoporosis Due to Spaceflight Gaps that included brief conclusions of completed tasks as they relate to closing the Gaps. Having such a summary of achieved results and how they help towards closure of the Gap and expected outcomes of ongoing or planned tasks would have allowed the SRP to better evaluate whether the Risks are addressed in a comprehensive manner.

The SRP was enthusiastic about ongoing efforts to assess the suitability of ultrasound to monitor rates of bone changes, fracture detection, and fracture healing during flights.

VII. 2012 Bone and Muscle Risk SRP Research Plan Review: Statement of Task for the Risk of Bone Fracture and the Risk of Early Onset Osteoporosis Due to Spaceflight

The 2012 Bone and Muscle Risk Standing Review Panel (SRP) is chartered by the Human Research Program (HRP) Chief Scientist. The purpose of the SRP is to review the Human Health Countermeasures (HHC) Element section of the HRP's Integrated Research Plan, Revision D (IRP Rev. D) which is located on the Human Research Roadmap (HRR) website (http://humanresearchroadmap.nasa.gov/). Your report will be provided to the HRP Chief Scientist.

The 2012 Bone and Muscle Risk SRP is charged (to the fullest extent practicable) to:

- 1. Evaluate the ability of the IRP Rev. D to satisfactorily address the Risk by answering the following questions:
 - A. Have the proper Gaps been identified to address the Risk?
 - i) Are all the Gaps relevant?
 - ii) Are any Gaps missing?
 - B. Has the appropriate target for closure for the Gap been identified?
 - i) Are the interim stages appropriate to close the Gap?
 - C. Have the proper Tasks been identified to fill the Gaps?
 - i) Are the Tasks relevant?
 - ii) Are any Tasks missing?
- 2. Identify the strengths and weaknesses of the IRP Rev. D, *and* identify remedies for the weaknesses, including answering these questions:
 - A. Is the Risk addressed in a comprehensive manner?
 - B. Are there obvious areas of potential integration across disciplines that are not addressed?
- 3. Please evaluate the progress in the IRP Rev. D since your 2011 SRP meeting.
- 4. Please comment on any important issues that are not covered in #1, #2, or #3 above. If a charge addendum is provided, please address each of the questions as fully as possible.

Additional Information Regarding This Review:

- 1. Expect to receive review materials at least four weeks prior to the meetings.
- Participate in a 2012 Bone and Muscle Risk SRP conference call to discuss any issues, concerns, and expectations of the review process approximately three weeks prior to the meeting.
 - A. Discuss the 2012 Bone and Muscle Risk SRP Statement of Task and address questions about the SRP process.

- B. Identify any issues the 2012 Bone and Muscle Risk SRP would like to have answered prior to or during the meeting.
- 3. Attend the 2012 Bone and Muscle Risk SRP meeting at NASA JSC on October 24 25, 2012.
 - A. Attend Element or Project presentations, question and answer session, and briefing.
 - B. Prepare a draft report that addresses each of the evaluation criteria listed in the panel charge. Debrief the HRP Chief Scientist and a representative from the HHC Element on the salient points that will be included in the final report and specifically the items in the panel charge.
- 4. Prepare a draft final report (within one month of the site visit debrief) that contains a detailed evaluation of the current IRP specifically addressing items #1, #2, #3, and #4 of the SRP charge. The draft final report will be sent to the HRP Chief Scientist and he will forward it to the appropriate Element for their review. The HHC Element and the HRP Chief Scientist will have 10 business days to review the draft final report and identify any misunderstandings or errors of fact and then provide official feedback to the SRP. The SRP will have 10 business days to address any issues and finalize the 2012 SRP Final Report. The 2012 SRP Final Report will be submitted to the HRP Chief Scientist and copies will be provided to the HHC Element that sponsors the bone and muscle disciplines and also made available to the other HRP Elements. The 2012 SRP Final Report will be made available on the Human Research Roadmap public website (http://humanresearchroadmap.nasa.gov/).

VIII. 2012 Bone and Muscle Risk Standing Review Panel Roster

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